

# Considerations of sex and gender dimensions by research ethics committees: a scoping review

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Despite a growing consensus on the importance of integrating sex and gender in health research, research across disciplines continues to be conducted and reported without a gender focus. Research ethics committees (RECs) can play a particularly powerful role in identifying the gender gaps at an early stage of the development of research protocols. Their role is missing in the dialogue related to improving gender awareness and analysis in health research. A scoping review was conducted to examine the extent to which RECs discuss and consider the inclusion and analysis of sex and gender in health research and to examine the literature regarding the gender balance of RECs. The limited literature around gender and research ethics reveals the power and potential of RECs to ensure that gender dimensions are thoughtfully included in health research, and sheds light on the gaps that exist. These include an under-representation of women on RECs, a lack of awareness of the importance of gender-related aspects in health research and a paucity of gender-related training to RECs. Guidelines such as the Sex and Gender Equity in Research guidelines are required for RECs to strengthen the ways in which health research is gendered from conception of a research protocol to its publication.

**Keywords:** ethics committees research, ethics review, gender, gender and sex, research ethics guidelines, pregnant women.

## Introduction

Despite an indisputable recognition of the importance of sex and gender dimensions in health research,<sup>1</sup> women continue to be under-represented in clinical and preclinical research, and sex and gender aspects continue to be understudied as a matter of routine.<sup>2,3</sup> By deciding what research is funded, ethically approved and published, gatekeepers in the research system, including research funding agencies, research ethics committees (RECs)—note that we use the terms RECs and institutional review boards (IRBs) interchangeably to mean any committee established by an organisation or institution to review the ethical aspects of research with human beings—and academic journals play a pivotal role in defining quality, rigour and, ultimately, what constitutes knowledge. In recent years, accountability for academic journals has been raised by the creation of the Sex and Gender Equity in Research (SAGER) guidelines.<sup>4</sup> Several funding agencies have endorsed these guidelines; others have included gender-responsive language in their grant-making mechanisms.<sup>5–7</sup> However, RECs' role in improving the gender knowledge gap remains absent,<sup>8</sup> even though they can play a particularly

powerful role in addressing the gender gaps and biases in research protocols at an early stage. We undertook a scoping review to examine the documented practices of RECs with respect to integration of sex and gender dimensions in health research. We aimed to understand the extent to which RECs deliberate on gender dimensions in research protocols, for example, considering the gendered aspects of inclusion, risk and vulnerability of research participants. Corollary to that question, we also gathered data from the literature regarding the gender balance of RECs.

## Methods

We developed several specific search strings in PUBMED, namely, ((Ethics committees research[MeSH Major Topic]) AND (review)) AND (gender); ((Ethics committees research[MeSH Major Topic]) AND (review)) AND (sex); (gender[MeSH Major Topic]) AND (ethics review[MeSH Major Topic]); Gender AND "ethics review"; (Ethics Committees, Research[MeSH Major Topic]) AND (sexism[MeSH Major Topic]); ("ethics committees, research"[MeSH Major Topic]) AND ((gender[Title/Abstract] OR sex[Title/Abstract])

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OR pregnan\*[Title/Abstract] OR Gay[Title/Abstract] OR Lesbian[Title/Abstract] OR Transgender[Title/Abstract] OR women[Title/Abstract] OR men[Title/Abstract])). However, these search strings identified only 13 relevant articles. We then used a broader search string (“(Ethics committees research [MeSH Major Topic]) AND review”) in PUBMED and supplemented it with the search string (“Research ethics committee” and “gender”) in Google Scholar. We limited our search to articles published in English after the year 2000, because advocacy for gender-sensitive research has been particularly visible only in the past two decades.<sup>4,5,7</sup> We included articles whose titles or abstracts mentioned terms such as gender, evaluation, recommendations, description, roles, activities, challenges, perspectives, process or methodological concerns, in relation to ethics review or ethics review committee(s). Articles that reviewed ethics guidelines in particular settings, such as disasters or internet-based research or gender-based violence (GBV), were also included. Excluded from our review were articles that compared reviews across several ethics committees, administrative or procedural issues, as well as articles related to streamlining ethics review, ethical concerns related to research methodology and research governance more broadly. Although articles describing the historical aspects of ethics committees could shed light on why gender issues are not routinely considered by ethics committees, we first wished to establish that assumption, before dwelling on the ‘why’, and therefore excluded them as well. We also excluded conference abstracts and book reviews. Data from included articles were extracted into a data extraction sheet (see Supplementary Material 1) and a descriptive analysis was applied.

## Findings

The search strategy identified 1483 possible articles. See Figure 1 for a schematic flowchart of the scoping review output. An initial screening of the titles shortlisted 201 articles, from which 133 were excluded after abstract review. Of the remaining 68 articles, 10 duplicate titles were removed. Fifteen additional articles were excluded after reading the full text, for not meeting the inclusion criteria. In addition to the 43 articles that met the inclusion criteria, 13 additional articles were identified through the references of the included articles, resulting in a total of 56 articles included for review. Of these, 16 articles were commentaries, philosophical analyses or reviews of published literature, ethics guidelines or policies and provided a theoretical consideration of what the ethics committees ought to focus on. The remaining 40 articles were original research and included primary data: seven used a case study approach to identify ethical concerns or describe decision-making processes relating to review of research, or to demonstrate the role that a feminist approach can play in guiding decision-making by RECs; surveys, interviews or focus group discussions with researchers, REC members or Chairs of RECs were used in 14 studies to collect data on the composition of RECs or the content of their review; observations of REC meetings and/or analyses of their outputs to describe the content of their review or the decision-making processes of RECs using ethnographic approaches were used in 22 studies. Some articles used more than one approach. Of the 56 articles reviewed, the majority (47) were published after 2010 and only 16 articles were authored by researchers from low- and middle-income countries.

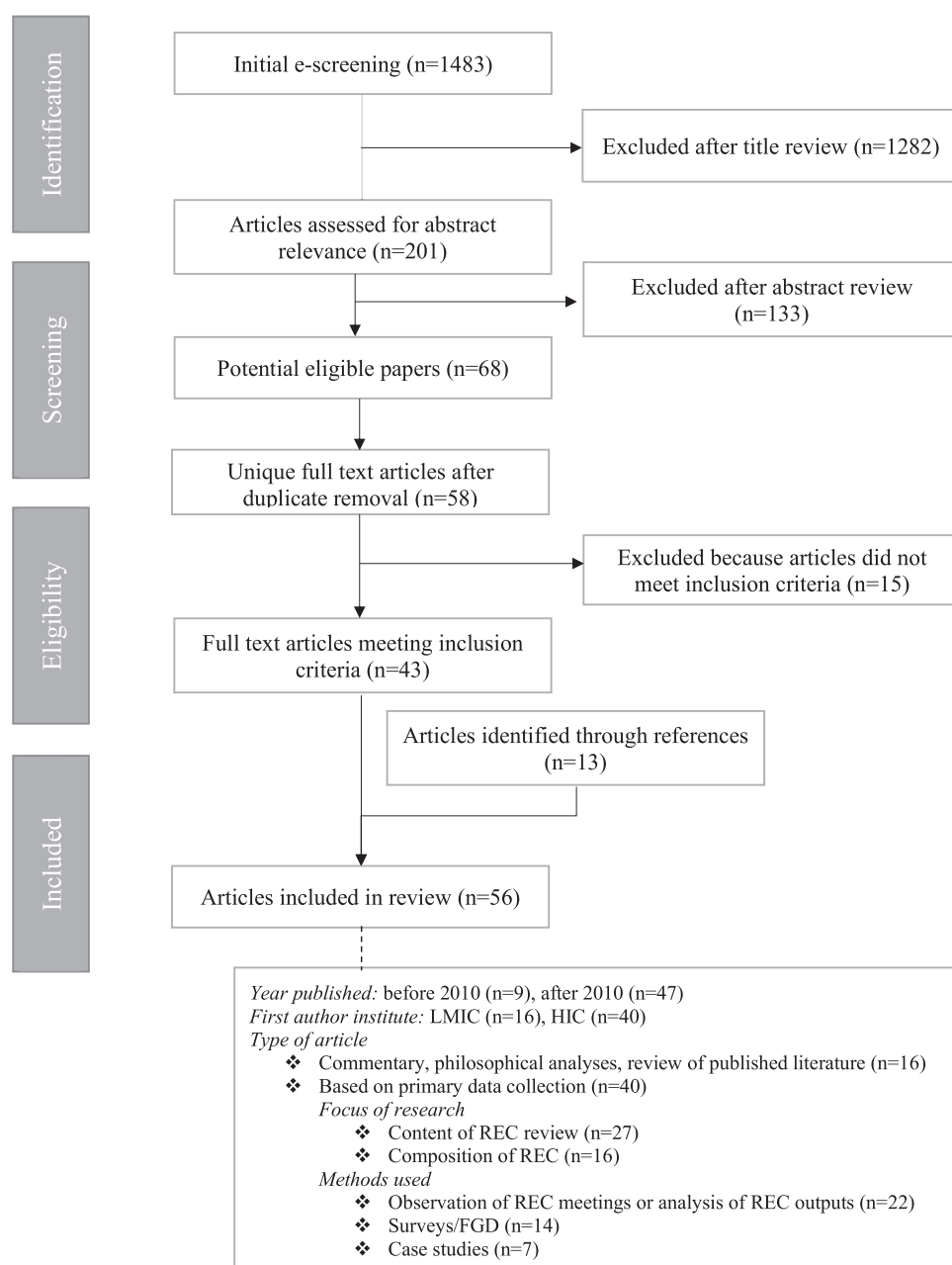
## Consideration of gender (or lack thereof) by RECs

Of the 56 papers included in this review, below we discuss the 27 publications (including two reviews of published literature<sup>9,10</sup>) that described the issues raised by RECs during review of protocols. Surveys or interviews with researchers or REC members were used in eight studies<sup>11–18</sup> and recommendations provided by RECs and/or minutes or observations of REC meetings (hereafter, collectively called REC outputs) were analysed in 17 studies.

One review of published literature, one survey and three analyses of REC outputs specifically reported on or mentioned sex and gender (non)consideration by RECs.<sup>9,16,19–21</sup> Ballantyne and Rogers<sup>16</sup> reported that Chairs of Australian RECs, when surveyed, opined that research should not be impeded on the grounds of sex inequities among research participants and they did not play an active role in monitoring inclusion of men and women in research. Moerman et al.,<sup>19</sup> after observing the practices of 10 ethics committees in five European countries, noted that they ‘paid only limited attention to gender equality in their method of working’. A (re)analysis, using a sex and gender lens, of protocols already approved by one REC, found that only 2% of researchers had indicated they would study sex or gender impact on their primary outcome, although the protocols included conditions or diseases likely to have sex- or gender-based differences in some aspect that was being studied.<sup>20</sup> Alirio et al.<sup>21</sup> analysed the issues raised by one REC during an infectious disease outbreak, and discussed the justice issues involved when pregnant women are excluded from relevant research. Refolo et al.,<sup>9</sup> through a review of literature, suggested that a lack of attention to gender issues during an ethics review of research that uses e-recruitment could result in non-representative sampling and differential participation of women and men.

None of the remaining seven surveys or the 15 studies that analysed REC outputs, whether through primary or secondary data analysis, reported on gender considerations. In relation to the surveys, where open-ended questions were included in the study design, respondents identified selection of participants<sup>15</sup> or (non)representativeness<sup>14</sup> as an ethical concern, as well as privacy, risk/benefits and standards of care, among others,<sup>11,12</sup> but did not explicitly mention the gender dimensions of these. Tansey et al.,<sup>17</sup> exploring differences in REC reviews of disaster-related research from non-disaster research, discussed the intersectionality of vulnerability, yet did not discuss gender. A survey of local RECs that reviewed multicentric research<sup>13</sup> focused on cultural, linguistic, socioeconomic and geographic variables but did not discuss local gender norms and issues. One survey-discussed later-explored REC concerns when reviewing research on GBV.<sup>18</sup>

A primary focus of RECs on principles of autonomy, beneficence or ethics as harm and benefits was reported in seven studies that analysed RECs outputs,<sup>22–28</sup> but none considered equitable recruitment, equitable distribution of risks and benefits, fair participation and/or justice issues under which gender would fall. Another five studies reported on the concerns of RECs around issues of fair participation or related criteria such as inclusion criteria, recruitment criteria, representativeness, legitimacy and appropriate risk benefit analysis,<sup>10,29–32</sup> with none mentioning sex or gender. A case study of a REC for ‘tribal nations’ described its role vis-a-vis culture and norms in reviewing multicentric research,



**Figure 1.** Schematic flowchart of the scoping review methods and outcomes. FGD, focus group discussion; HIC, high-income country; LMIC, low- and middle-income country.

but did not include sex and gender considerations.<sup>33</sup> A study analysing the meeting minutes of two South African RECs showed that ‘fair participation’ ranked last in order of importance.<sup>34</sup> Gender was similarly left out of an analysis of the concerns raised by one REC when reviewing research involving a vulnerable, minority population,<sup>35</sup> although vulnerability is a highly gendered notion.<sup>36</sup>

Sikweyiya and Jewkes,<sup>18</sup> in a survey conducted in the context of GBV, found that RECs often hesitated to approve such research, even though it might have benefitted women experiencing GBV, in the mistaken belief that the interests of a vulnerable popu-

lation were being protected. Pregnant women have also often been excluded from health research on the basis of perceived vulnerability, and fear of potential risks to the unborn fetus.<sup>37–39</sup> RECs are not the only culprits in excluding pregnant ‘vulnerable’ women: regulatory and legal aspects also prevent their inclusion in research, even when RECs recommend their inclusion.<sup>21</sup> Nevertheless, van der Zande et al.<sup>40</sup> have recommended that RECs should require researchers to provide justifications for excluding pregnant women from research. Payne has suggested the inclusion of maternal-foetal medicine experts in a REC membership,

and improving their understanding of research regulations as a means of providing additional protection to pregnant women to safeguard their research interests.<sup>41</sup>

### Strengthening RECs to recognise sex- and gender-related ethical concerns

Several papers included in this review highlight the potential role of RECs in promoting integration of sex and gender considerations in health research, through requiring researchers to be cognizant of these issues and addressing them before submitting their research protocols for review.<sup>20,42,43</sup> These authors have suggested training RECs to recognise sex- and gender-related ethical concerns, the use of checklists and development of decision trees. Other tools for RECs to assess gender issues in a systematic manner mentioned in the literature included questions on sex and gender in the ethics application form<sup>16</sup> and guidelines and training on assessing gender aspects in research protocols, in addition to including more women on RECs.<sup>19,20,44</sup> De Vreis et al.<sup>45</sup> have pointed out, in the context of a review of sociobehavioural and economic sciences, that to understand how to improve the gaps in the way that RECs function, one must first have data from direct observation of RECs at work. They found that RECs are often reticent to share information about discussions that occur in their closed deliberations. Silaigwana and Wassenaar<sup>34</sup> have also reported such reticence on the part of RECs. Morton<sup>29</sup> called for more transparency on how RECs make decisions, and as well as other authors,<sup>29,45–47</sup> used qualitative and ethnographic methods to study how RECs make decisions, and have provided recommendations for understanding, improving and evaluating the functions of RECs. Evaluation frameworks for RECs can also be gender blind. An evaluation framework for RECs developed through an analysis of ethics guidelines and key ethics documents<sup>48</sup> included gender equality in the composition of RECs but did not include training on gender issues, nor did the framework suggest evaluating RECs based on whether or not they conduct sex- and gender-based analysis. Similarly, Coleman and Bouësseau,<sup>49</sup> when discussing outcome measures to assess the functioning of ethics committees, focused very narrowly on whether ethics committees are actually protecting research participants, and did not include outcome measures related to fair participation.

### Gender (im)balance in RECs

Of the 16 papers describing the composition of RECs, eight were based on surveys, two on reviews of literature, four on reviews of documents, five were case studies and three were opinion pieces or commentaries. Two of the 16 papers (both from Egypt) reported a balanced representation of men and women in RECs in Egypt (without defining ‘balanced’),<sup>50,51</sup> while four papers made no mention of representation of women in the RECs or the presence of gender expertise therein.<sup>28,52–54</sup> The remaining 10 articles highlighted the lack of attention to an equal representation of women in RECs, including in high-income countries.<sup>10,11,19,44,55–60</sup> Of these, four also explored the role of laws, regulations, biases and structural imbalances in the scientific field on the composition of ethics committees.<sup>19,55,56,60</sup> (Note that a gender imbalance

was also reported in 2006, in the International Bioethics Committee [IBC] established by UNESCO.<sup>60</sup> The 2020–2021 IBC, however, has a better representation of women: 21 women and 15 men.)

In 2011, in an opinion piece on the theoretical shortcomings of RECs, Yaghoobi<sup>55</sup> stated that having a lone woman’s voice on a REC pays lip service to gender balance and may not affect the decision of the majority. A review of literature on African RECs (1996 and 2014)<sup>10</sup> found that women’s participation ranged from 15.2% to 54% in 5 of 23 studies that described RECs’ gender composition,<sup>11,56–59</sup> despite the existence of national guidelines requiring gender-balanced RECs in some countries.<sup>61,62</sup> Comparing the composition and educational background of members of RECs in the USA and South Africa, Klitzman<sup>11</sup> noted that in both countries, men on RECs typically had higher educational qualifications than women, were more likely to be white and to be appointed chairpersons. Moodley and Myer drew a similar conclusion in their analysis of 12 RECs in South Africa.<sup>56</sup> An analysis of the practices of 10 RECs from five European countries in 2007<sup>19</sup> revealed that, while all the RECs did include women in their composition, only Austria had a law/regulation, and Ireland a national guideline, that required representation of women and men on the Committee, although none required ‘equal’ representation, and none required gender expertise. A literature review using ‘public health research’ and ‘gender’ and ‘ethics’ as the search string concluded that the composition of RECs should be more representative of society and pointed to the need for more awareness, training and guidelines in this area.<sup>44</sup> In addition to having a better representation of women’s competences, experiences and perspectives, Dickenson<sup>60</sup> recommended that RECs must include gender expertise as well. A guide for REC members issued by the Steering Committee on Bioethics of the Council of Europe in 2010<sup>63</sup> has recommended a balanced representation of women in ethics committees, but does not speak about gender expertise.

### Discussion

Our review reveals the conspicuous absence of attention to sex and gender by RECs, an under-representation of women in RECs and the existence of only a few regulations, rules or guidelines that require RECs to evaluate research using a gender lens or to include a balanced representation of women or gender expertise within their composition. We also found that pregnant women were being excluded by RECs from research even when it was relevant to their needs, often due to being considered vulnerable,<sup>64</sup> despite the existence of ethics guidelines on the inclusion of vulnerable populations in health research.<sup>65</sup>

From a public health perspective, gender is considered a social determinant of health, having vital implications for one’s health and well-being.<sup>66</sup> ‘Breaking down data by age, sex and income group is vital for understanding who is being left behind and why.’<sup>67</sup> But data disaggregated by sex- and gender-sensitive research continues to be scant, which is not only a scientific but also a justice issue. RECs can respond to this justice issue by ensuring that gender issues are adequately considered across all aspects of research at an early stage. Our review shows that this does not often happen.



Our review relies on secondary data, therefore it is possible that REC deliberations on sex and gender issues were not reported in the reviewed articles, or that protocols reviewed by RECs already satisfied sex- and gender-related requirements and were therefore neither discussed nor reported. Both possibilities seem highly unlikely given the existing literature on gender gaps and biases in the research system. It is more likely that REC discussions were reported at a higher level of abstraction under the broad heading of fair participation without unpacking the concept from a gender perspective. The concept of fair participation hides the reality that within groups of potential participants to whom fairness is owed (e.g. older people, lower socioeconomic groups), women are often more disadvantaged than men, and often under-represented. In our opinion, sex and gender as variables are particularly important to comment on independently when reviewing research because of the compounded disadvantage that women can experience due to their gender and other marginalisation resulting in persistent under-representation in health research.

A gender-blind ethical evaluation can inadvertently reinforce injustices, may prevent women from benefitting from the outcomes of research (an issue of beneficence) and potentially harm the interests of women at a policy level (maleficence). RECs, by overlooking evaluation of gender dimensions, are failing in their responsibility to uphold the ethical principles of beneficence, non-maleficence and justice. Pregnant women and those belonging to stigmatised groups, including those subjected to GBV, are often excluded from research, even that which may have a direct benefit, because they are considered 'vulnerable' by RECs.<sup>18</sup> An analysis of the recent vaccine rollouts for COVID-19 demonstrates that pregnant women have again been excluded from the benefits of research while bearing a greater risk of serious illness and death.<sup>37,68</sup> RECs, in the belief that excluding these groups from research is a form of 'protection', undermine the decision-making ability of these women, and upend the fourth ethical principles of autonomy. Correcting these failures is not only the responsibility of RECs, but also of all stakeholders of the health research system that have the responsibility to support RECs.

There is a growing recognition that a gender lens must be applied by RECs when reviewing research; they must be gender-trained and require equal representation of women in their membership.<sup>69</sup> Although there is no empirical evidence, it is likely that a REC with a balanced representation of women would frame issues differently<sup>60,70</sup> and be more cognizant of gender-related issues. Women are often under-represented on ethics committees, either because of a lack of national and local laws and regulations or due to structural reasons,<sup>60</sup> such as the discriminatory demographic factors that continue to result in less representation of women at higher levels of science and medicine.<sup>71</sup> Current data are needed to know whether ethics committees have become more gender-balanced and whether knowledge and expertise in gender-related issues is now sought.

Regulations and guidelines are also influential. Gender balance as an issue relevant to the composition of RECs is mentioned only in the guidance document published by the WHO.<sup>72</sup> The Council of International Organizations of Medical Sciences (CIOMS) guidelines<sup>65</sup> do not underline the need for RECs to have an equal representation of men and women. Gender training is not mentioned in any ethics guideline<sup>65,72-74</sup> and is a gap. While

many ethics guidelines require RECs to pay specific attention to justice and vulnerability issues, sex and gender considerations are usually not included.<sup>65,75</sup> Updated or additional research ethics guidance that addresses concerns related to sex and gender aspects of risks, benefits and justice can shape the ethical standards and guide the work of RECs. Recent nuanced understanding of the concept of vulnerability and ethics guidelines for managing them more broadly,<sup>65</sup> or the ethically responsible, socially just and respectful inclusion of the interests of pregnant women in research,<sup>38,39,65</sup> are steps in the right direction, and must be embraced by RECs.

A lack of both specific gender tools and a specific gender focus in currently proposed evaluation frameworks for RECs<sup>48,49</sup> constitute important gaps. Important outcomes are whether RECs reviewing research improved participation by women in research and a better integration of sex and gender dimensions throughout the research cycle.<sup>43</sup> It is worth considering whether the model used by Eckstein<sup>76</sup> in relation to race and ethnicity could be adapted to review research from a gender perspective. Another possible direction is the adaptation of the SAGER guidelines<sup>4</sup> for use by RECs. This would harmonise the efforts by several key gatekeepers from research design to publication.

This scoping review, although based only on capturing English language publications from two databases, points to an important gap, and provides a rationale for more concerted action by all stakeholders of research to strengthen RECs to include sex- and gender-based considerations when reviewing research. An important gap is the lack of literature on when (and how) RECs should focus on sex and gender issues beyond the binary as an ethical concern, that is, whether (and how) they should ask for fair inclusion of intersex, transgender and non-binary individuals in research, given the compounded marginalisation, stigmatisation and adverse legal environment in many countries. This aspect warrants further investigation.

## Conclusion

This review highlights the role of RECs in addressing the gender bias in research. As responsible gatekeepers of research they have a responsibility to be cognizant of intersectional gender dynamics, gender biases in research and the ethical implications thereof, so that gender dimensions can be thoughtfully included in health research at an early stage. More research is required to understand whether and how RECs consider gender issues in their discussions. Development of tools and evaluation criteria for inclusion of gender dimensions in research can support RECs in this endeavour.

## Supplementary data

Supplementary data are available at *International Health* online (<http://inthehealth.oxfordjournals.org>).

**Author's contributions:** AS and SH conceived the study; AS and EL independently reviewed the articles shortlisted for the review and drafted the manuscript; SH and CS critically reviewed and provided substantial input

and revised the manuscript for intellectual content. All the authors have read and approved the final version of the manuscript and take responsibility for the content of the paper.

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## References

- Welch V, Doull M, Yoganathan M, et al. Reporting of sex and gender in randomized controlled trials in Canada: a cross-sectional methods study. *Res Integr Peer Rev*. 2017;2(1):15. DOI: 10.1186/s41073-017-0039-6.
- Yakerson A. Women in clinical trials: a review of policy development and health equity in the Canadian context. *Int J Equity Health*. 2019;18(1):1–8.
- Mazure CM, Jones DP. Twenty years and still counting: including women as participants and studying sex and gender in biomedical research. *BMC Women's Health*. 2015;15(1):94.
- Heidari S, Babor TF, de Castro P, et al. Sex and Gender Equity in Research: rationale for the SAGER guidelines and recommended use. *Res Integr Peer Rev*. 2016;1:2. DOI 10.1186/s41073-016-0007-6.
- NOT-OD-15-102: Consideration of Sex as a Biological Variable in NIH-funded Research. Available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html> [accessed December 3, 2020].
- Gender - H2020 Online Manual. Available at [https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/gender\\_en.htm](https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/gender_en.htm) [accessed December 3, 2020].
- CIHR-IRSC. Available at <https://cihr-irsc.gc.ca/e/50837.html> [accessed December 3, 2020].
- Arnegard ME, Whitten LA, Hunter C, et al. Sex as a biological variable: a 5-year progress report and call to action. *J Womens Health*. 2020;29(6):858–64.
- Refolo P, Sacchini D, Minacori R, et al. E-recruitment based clinical research: notes for Research Ethics Committees/Institutional Review Boards. *Eur Rev Med Pharmacol Sci*. 2015;19(5):800–4.
- Silaigwana B, Wassenaar D. Biomedical research ethics committees in sub-Saharan Africa: a collective review of their structure, functioning, and outcomes. *J Emp Res Hum Res Ethics*. 2015;10(2):169–84.
- Klitzman R. Views of the process and content of ethical reviews of HIV vaccine trials among members of US institutional review boards and south African research ethics committees. *Dev World Bioeth*. 2008;8(3):207–18.
- Hyder AA, Wali SA, Khan AN, et al. Ethical review of health research: a perspective from developing country researchers. *J Med Ethics*. 2004;30(1):68–72.
- Klitzman R, Pivovaro E, Murray A, et al. Local knowledge and single IRBs for multisite studies: challenges and solutions. *Ethics Hum Res*. 2019;41(1):22–31.
- Buchanan EA, Hvizdak EE. Online survey tools: ethical and methodological concerns of human research ethics committees. *J Emp Res Hum Res Ethics*. 2009;4(2):37–48.
- Atallah D, Moubarak M, el Kassis N, et al. Clinical research ethics review process in Lebanon: efficiency and functions of research ethics committees - results from a descriptive questionnaire-based study. *Trials*. 2018;19(1):1–15.
- Ballantyne AJ, Rogers WA. Fair inclusion of men and women in Australian clinical research: views from ethics committee chairs. *Med J Aust*. 2008;188(11):653–6.
- Tansey CM, Anderson J, Boulanger RF, et al. Familiar ethical issues amplified: how members of research ethics committees describe ethical distinctions between disaster and non-disaster research. *BMC Med Ethics*. 2017;18(1):1–12.
- Sikweyiya Y, Jewkes R. Perceptions about safety and risks in gender-based violence research: implications for the ethics review process. *Cult Health Sex*. 2011;13(9):1091–102.
- Moerman CJ, Haafkens JA, Söderström M, et al. Gender equality in the work of local research ethics committees in Europe: a study of practice in five countries. *J Med Ethics*. 2007;33(2):107–12.
- Freeman A, Stanko P, Berkowitz LN, et al. Inclusion of sex and gender in biomedical research: survey of clinical research proposed at the University of Pennsylvania. *Biol Sex Diff*. 2017;8(1):1–8.
- Alirio E, Kuesel AC, Guraiib MM, et al. Ethics review of studies during public health emergencies - The experience of the WHO ethics review committee during the Ebola virus disease epidemic. *BMC Med Ethics*. 2017;18(1):1–11.
- Bueno M, Brevidei MM, Cocarelli T, et al. Reasons for resubmission of research projects to the research ethics committee of a university hospital in São Paulo, Brazil. *Clinics*. 2009;64(9):831–6.
- Tersmette DG, Engberts DP. Problematic protocols: an overview of medical research protocols not approved by the LUMC medical ethics review committee. *AJOB Empirical Bioethics*. 2017;8(1):52–7.
- van Lent M, Rongen GA, Out HJ. Shortcomings of protocols of drug trials in relation to sponsorship as identified by Research Ethics Committees: analysis of comments raised during ethical review. *BMC Med Ethics*. 2014;15(1):1–9.
- Happo SM, Halkoaho A, Lehto SM, et al. The effect of study type on research ethics committees' queries in medical studies. *Res Ethics*. 2017;13(3-4):115–27.
- Hemminki E, Virtanen JI, Regushevskaya E. Decisions by Finnish Medical Research Ethics Committees. *J Emp Res Hum Res Ethics*. 2015;10(4):404–13.
- Martín-Arribas MC, Rodríguez-Lozano I, Arias-Díaz J. Ethical review of research protocols, experience of a research ethics committee. *Revista Española de Cardiología*. 2012;65(6):525–9.
- Suzuki M, Sato K. Description and evaluation of the research ethics review process in Japan: proposed measures for improvement. *J Emp Res Hum Res Ethics*. 2016;11(3):256–66.
- Morton J. "Text-work" in research ethics review: the significance of documents in and beyond committee meetings. *Account Res*. 2018;25(7-8):387–403.
- Decullier E, Lhéritier V, Chapuis F. The activity of French Research Ethics Committees and characteristics of biomedical research protocols involving humans: a retrospective cohort study. *BMC Med Ethics*. 2005;6:1–10.
- Angell EL, Bryman A, Ashcroft RE, et al. An analysis of decision letters by research ethics committees: the ethics/scientific quality boundary examined. *Qual Saf Health Care*. 2008;17(2):131–6.
- Kelleher E, Stanton A, Vale G, et al. Recurring themes arising during medical research ethics committee review. *Irish Med J*. 2013;106(6):184–5.

- 33 Angal J, Petersen JM, Tobacco D, et al. Ethics review for a multi-site project involving tribal nations in the northern plains. *J Emp Res Hum Res Ethics*. 2016;11(2):91–6.
- 34 Silaigwana B, Wassenaar D. Research ethics committees' oversight of biomedical research in South Africa: a thematic analysis of ethical issues raised during ethics review of non-expedited protocols. *J Emp Res Hum Res Ethics*. 2019;14(2):107–16.
- 35 Adams P, Wongwit W, Pengsaa K, et al. Ethical issues in research involving minority populations: the process and outcomes of protocol review by the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, Thailand. *BMC Med Ethics*. 2013;14:33. DOI: 10.1186/1472-6939-14-33.
- 36 UNICEF. The Impacts of the COVID-19 Outbreak Response on Women and Girls in the Democratic Republic of the Congo. DRC: Social Sciences Analytics Cell, 2021.
- 37 Heidari S, Goodman T. Critical Sex and Gender Considerations for Equitable Research, Development and Delivery of Covid-19 Vaccines. 2021. Geneva, Switzerland: World Health Organisation.
- 38 Pregnancy Research Ethics for Vaccines, Epidemics and New Technologies (PREVENT). Available at <http://vax.pregnancyethics.org>. [accessed January 9, 2022].
- 39 Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC). Task Force Report to Secretary Health and Human Services, USA. 2018. Available at [https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC\\_Report.pdf](https://www.nichd.nih.gov/sites/default/files/2018-09/PRGLAC_Report.pdf) [accessed January 9, 2022].
- 40 van der Zande ISE, van der Graaf R, Oudijk MA, et al. Vulnerability of pregnant women in clinical research. *J Med Ethics*. 2017;43(10):657–63.
- 41 Payne P. Including pregnant women in clinical research: practical guidance for institutional review boards. *Ethics Hum Res*. 2019;41(6):35–40.
- 42 Duffy KA, Ziolek TA, Epperson CN. Filling the regulatory gap: potential role of institutional review boards in promoting consideration of sex as a biological variable. *J Womens Health*. 2020;29(6):868–75.
- 43 Segarra I, Modamio P, Fernández C, et al. Sex-divergent clinical outcomes and precision medicine: an important new role for institutional review boards and research ethics committees. *Front Pharmacol*. 2017;8(JUL):1–10.
- 44 Lawrence K, Rieder A. Methodologic and ethical ramifications of sex and gender differences in public health research. *Gend Med*. 2007;4(SUPPL. B):S96–S105.
- 45 de Vries R, DeBruin DA, Goodgame A. Ethics review of social, behavioral, and economic research: where should we go from here? *Ethics Behav*. 2004;14(4):351–68.
- 46 de Jong JP, van Zwieten MCB, Willems DL. Ethical review from the inside: repertoires of evaluation in research ethics committee meetings. *Sociol Health Illn*. 2012;34(7):1039–52.
- 47 Dixon-Woods M, Angell E, Ashcroft RE, et al. Written work: the social functions of research ethics committee letters. *Soc Sci Med*. 2007;65(4):792–802.
- 48 Scherzinger G, Bobbert M. Evaluation of research ethics committees: criteria for the ethical quality of the review process. *Account Res*. 2017;24(3):152–76.
- 49 Coleman CH, Bouësseau MC. How do we know that research ethics committees are really working? The neglected role of outcomes assessment in research ethics review. *BMC Med Ethics*. 2008;9:1–7.
- 50 Younis IM. Overview of research committees status in Egypt: challenges, aspirations and current situation. *Account Res*. 2015;22(4):221–35.
- 51 Abdel-Aal W, Ghaffar EA, el Shabrawy O. Review of the medical research ethics committee (MREC), national research center of Egypt, 2003–2011. *Curr Med Res Opin*. 2013;29(10):1411–7.
- 52 Minacori R, Refolo P, Sacchini D, Spagnolo AG. Research ethics committees and clinical research in Italy: where are we going? *Eur Rev Med Pharmacol Sci*. 2015;19:481–5.
- 53 Doppelfeld E, Hasford J. Medical research ethics committees in the Federal Republic of Germany: establishment and integration into medical research. *Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz*. 2019;62(6):682–9.
- 54 Sacarlal J, Muchanga V, Mabutana C, et al. Research ethics review at University Eduardo Mondlane (UEM)/Maputo Central Hospital, Mozambique (2013–2016): a descriptive analysis of the start-up of a new research ethics committee (REC). *BMC Med Ethics*. 2018;19(1):37.
- 55 Yaghoobi M. Theoretical shortcomings of institutional review boards and possible solutions. *Archi Iran Med*. 2011;14(3):202–3.
- 56 Moodley K, Myer L. Health research ethics committees in South Africa 12 years into democracy. *BMC Med Ethics*. 2007;8:1–8.
- 57 Ikingura JK, Kruger M, Zeleke W. Health research ethics review and needs of institutional ethics committees in Tanzania. *Tanzania Health Res Bull*. 2007;9(3):154–8.
- 58 Matar A, Silverman H. Perspectives of Egyptian research ethics committees regarding their effective functioning. *J Emp Res Hum Res Ethics*. 2013;8(1):32–44.
- 59 Nyika A, Kilama W, Chilengi R, et al. Composition, training needs and independence of ethics review committees across Africa: are the gate-keepers rising to the emerging challenges? *J Med Ethics*. 2009;35(3):189–93.
- 60 Dickenson D. Gender and ethics committees: where's the "different voice"? *Bioethics*. 2006;20(3):115–24.
- 61 NHREC Ethics Guidelines, Department of Health, S. Africa. Available at <https://www.samrc.ac.za/sites/default/files/attachments/2021-04-12/ResearchEthicsPolicy.pdf> [accessed January 13, 2022].
- 62 Mashalla YJS, Shija JK, Kitua AY, et al. Guidelines of Ethics for Health Research in Tanzania. Dar es Salaam: National Health Research Ethics Committee, 2009.
- 63 CDBI. Guide for Research Ethics Committee Members: Steering Committee on Bioethics (CDBI) of the Council of Europe. 2012. Available at <https://www.coe.int/en/web/bioethics/guide-for-research-ethics-committees-members> [accessed January 13, 2022].
- 64 Krubiner CB, Faden RR, Karron RA, et al. Pregnant women & vaccines against emerging epidemic threats: ethics guidance for preparedness, research, and response. *Vaccine*. 2021;39(1):85–120.
- 65 2016 International ethical guidelines for health-related research involving humans - CIOMS. Available at <https://cioms.ch/publications/product/international-ethical-guidelines-for-health-related-research-involving-humans/> [accessed November 28, 2020].
- 66 Commission on Social Determinants of Health. Closing the Gap in a Generation: health equity through action on the social determinants of health: final report: executive summary. World Health Organization. 2008. Available at <https://apps.who.int/iris/handle/10665/69832> [accessed January 9, 2022].
- 67 @DrTedros. Ahead of #WorldHealthDay, @WHO releases new health data showing that women outlive men everywhere in the world—particularly in wealthy countries. Breaking down data by age, sex and income group is vital for understanding who is being left behind and why. <http://bit.ly/WorldHealthStatistics2019>. <https://twitter.com/drtedros/status/1113850913054130176>. Posted April 4, 2019. Retrieved January 9, 2022.

- 68 Heidari S, Durrheim DN, Faden R, et al. Time for action: towards an intersectional gender approach to COVID-19 vaccine development and deployment that leaves no one behind. *BMJ Global Health*. 2021;6(8):1–9.
- 69 Nabil AMF. The Ethicist's Practical Guide to the Evaluation of Preclinical Research from a Sex and Gender Perspective. University of Zaragoza, Spain. 2021. doi:10.13140/RG.2.2.12655.97443. Available at <https://www.researchgate.net/publication/349462836> [accessed January 9, 2022].
- 70 Institute of Medicine. Women and Health Research : Ethical and Legal Issues of Including Women in Clinical Studies, Volume 1 ( Mastroianni A, Faden R Federman D, eds). National Academies Press; 1994.
- 71 European Commission. Directorate-General for Research and Innovation, She figures 2018, Publications Office, 2019 <https://data.europa.eu/doi/10.2777/936> [accessed January 9, 2022].
- 72 World Health Organization. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants. 2011. Available at <http://apps.who.int/iris/bitstream/handle/10665/44783> [accessed January 9, 2022].
- 73 WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects – WMA – The World Medical Association. Available at <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> [accessed November 29, 2020].
- 74 International Bioethics Committee (IBC). Available at <https://en.unesco.org/themes/ethics-science-and-technology/ibc> [accessed November 29, 2020].
- 75 Mezinska S, Kakuk P, Mijaljica G, et al. Research in disaster settings: a systematic qualitative review of ethical guidelines. *BMC Med Ethics*. 2016;17(1):1–11.
- 76 Eckstein L. Beyond racial and ethnic analyses in clinical research: a proposed model for Institutional Review Boards. *Food Drug Law J*. 2011;66(2):243–63.